MOTION FILED

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No. 06-372

IN THE

Supreme Court of the United States

FERRING B.V. and
AVENTIS PHARMACEUTICALS, INC.,
Petitioners,

v.

BARR LABORATORIES, INC.,
Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

MOTION FOR LEAVE TO FILE BRIEF AND BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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MOTION FOR LEAVE TO FILE BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

Pursuant to Rule 37.2 of the Rules of this Court, the Washington Legal Foundation (WLF) respectfully moves for leave to file the attached brief as *amicus curiae* in support of Petitioners. Counsel for Petitioners has consented to the filing of this brief. Counsel for Respondent declined to consent, thereby necessitating the filing of this motion.

WLF is a non-profit public interest law and policy center with supporters in all 50 states. WLF regularly appears before federal and state courts to promote economic liberty, free enterprise, and a limited and accountable government.

In particular, WLF has appeared in numerous federal and state courts in cases raising issues related to health care delivery. *See, e.g., Pharmaceutical Research and Manufacturers of America v. Walsh*, 538 U.S. 644 (2003). WLF successfully challenged the constitutionality of Food and Drug Administration (FDA) restrictions on speech regarding off-label uses of FDA-approved products. *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dism'd*, 202 F.3d 331 (D.C. Cir. 2000). WLF also has participated in numerous court proceedings raising important issues regarding the scope and validity of pharmaceutical patents. *See, e.g., Purdue Pharma, L.P. v. Endo Pharmaceuticals, Inc.*, 438 F.3d 1123 (Fed. Cir. 2006) (opposing efforts to invalidate patent on grounds of inequitable conduct); *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331 (Fed. Cir. 2005), *cert. denied*, 126 S. Ct. 2887 (2006); *Pfizer, Inc. v. Dr. Reddy's Laboratories, Ltd.*, 359 F.3d 1361 (Fed. Cir. 2004); *Allergan, Inc. v. Alcon Laboratories, Inc.*, 324 F.3d 1322 (Fed. Cir.), *cert. denied*, 540 U.S. 1048 (2003).

WLF strongly supports providing patent protection to pharmaceutical manufacturers that develop new and useful drugs. WLF believes that if advances in health care are to continue, it is vital that companies that develop new drugs and medical devices be afforded a substantial period of exclusivity, during which potential competitors are not permitted to market the same product. That exclusivity period provides an economic incentive for new product development by ensuring that pharmaceutical companies that gamble the substantial sums necessary for the development of new therapies will be able to reap substantial rewards in those few instances in which their research and development expenditures bear fruit.

WLF also recognizes that Congress has imposed limits on patent rights and that those limits must be strictly enforced by the courts if competition is to be maintained. Nonetheless,

WLF believes that the Federal Circuit's decisions in this and similar cases – which have invalidated numerous important patents on inequitable conduct grounds – have the potential to undermine our nation's patent system if allowed to stand. WLF is concerned that the Federal Circuit's "inequitable conduct" case law has drifted far afield from its "unclean hands" roots. By lowering the bar for those charging patent invalidity due to inequitable conduct, the Federal Circuit has considerably increased the risks to those asserting patent rights and considerably reduced the market value of all patents. WLF is concerned that if the property rights of patent holders can be so easily eliminated, the public will quickly lose faith in the viability of our patent system.

WLF fully supports Petitioners' request that the Court grant review of both of the Questions Presented in this Petition. WLF writes separately in order to emphasize its particular concern over the first Question Presented and the Federal Circuit's expansion of what constitutes a "material" omission from a patent application.

WLF is filing this brief because of its interest in promoting the stability of the nation's patent system; it has no interest, financial or other, in the outcome of this lawsuit. Because of its lack of direct economic interests, WLF believes that it can assist the Court by providing a perspective that is distinct from that of any party.

For the foregoing reasons, the Washington Legal Foundation respectfully requests that it be allowed to participate in this case by filing the attached brief.

Respectfully submitted,

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October 6, 2006

QUESTION PRESENTED

Amicus curiae addresses the following issue only:

Whether the U.S. Court of Appeals for the Federal Circuit has improperly expanded the scope of the inequitable conduct doctrine by lowering the threshold of what constitutes "material" information that a patentee must disclose to the U.S. Patent and Trademark Office so as to include information that has no bearing on patentability.

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BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

INTERESTS OF *AMICUS CURIAE*

The interests of *amicus curiae* Washington Legal Foundation (WLF) are set forth in the motion accompanying this brief.[1]

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[1] Pursuant to Supreme Court Rule 37.6, WLF states that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than WLF and its counsel, contributed monetarily to the preparation and submission of this brief.

STATEMENT OF THE CASE

This case raises important issues regarding the circumstances under which it is appropriate for federal courts to decline to enforce an otherwise valid patent, on the grounds that the patent holder engaged in inequitable conduct before the U.S. Patent and Trademark Office (PTO).

Petitioners filed suit against Respondent Barr Laboratories, Inc. in 2002, alleging that Barr was infringing a patent issued in 1992 (the "Ferring Patent"). The invention describes a method for orally administering DDAVP (an antidiuretic drug used to treat diabetes insipidus). Prior to the invention, DDAVP was administered only through the nasal passages.

During proceedings before the PTO, an issue arose concerning whether the invention was anticipated by prior art. The examiners suggested that the inventor, Dr. Hans Vilhardt, submit "evidence from a non-inventor" regarding whether an earlier patent (the "Zaoral Patent") suggested oral administration of DDAVP for gastrointestinal absorption. Pet. App. 3a. In response, Vilhardt in 1986 submitted four declarations on that issue – two from himself and one each from Dr. Myron Miller and Dr. Paul Czernichow. *Id.* 3a-4a.

Later, in response to additional concerns raised by the Board of Patent Appeals and Interferences, Dr. Vilhardt in 1990 submitted five additional declarations to the effect that an 1973 article written by Ivan Vavra (the "Vavra reference"), even when read in combination with the Zaoral Patent, would not suggest the gastrointestinal absorption of DDAVP. These declarations were sworn to by the three 1986 declarants, as well as by Dr. Iain Robinson and Dr. Tomislav Barth. *Id.* 6a. There has been no suggestion in these proceedings that any of

the declarations was false. The PTO issued the Ferring Patent without elaboration in September 1991. Vilhardt assigned his patent rights to Petitioner erring B.V., which in turn signed an exclusive licensing agreement with Petitioner Aventis Pharmaceuticals, Inc. *Id.* 3a, 7a.

Petitioners filed suit after Barr announced in July 2002 that it intended to market a generic version of the compound at issue. *Id.* 7a. Barr moved for summary judgment, claiming that its marketing plans would not infringe the Ferring Patent and that the patent was invalid due to inequitable conduct before the PTO. In February 2005, the district court granted summary judgment on both grounds. *Id.* 50a-85a. The court concluded that the PTO "must have relied substantially" on the declarations of Drs. Czernichow, Robinson, and Barth in allowing the Ferring Patent. *Id.* 56a. The court noted that those declarations did not disclose that each of those three individuals had had prior business relationships with Ferring (albeit they had no business relationships at the time they signed their declarations): Dr. Czernichow had (unbeknownst to Dr. Vilhardt) served as a consultant to Ferring, Dr. Robinson had been employed by Ferring and was a friend of Dr. Vilhardt, and Dr. Barth had intermittently worked on Ferring-funded projects (albeit he was never compensated by Ferring). The court determined that their declarations were "highly material," *id.* 68a, and that the three declarants' relationships with Ferring were material as well. *Id.* 64a. It also determined that the failure to disclose those relationships was done with "an intent to deceive" the PTO. *Id.* 67a. The court then determined that the applicant's misconduct was "so culpable that the patent should be held unenforceable." *Id.* 68a.

A divided Federal Circuit affirmed. *Id.* 1a-49a. The appeals court explained that under established Federal Circuit

case law a patent will be declared unenforceable due to inequitable conduct if the alleged infringer can demonstrate that: (1) the applicant made an affirmative misrepresentation of *material* fact, or failed to disclose *material* information to the PTO; (2) the misrepresentation or omission was undertaken with *intent* to mislead; and (3) the applicant's conduct is sufficiently culpable to warrant a determination that the patent should be held unenforceable. *Id.* 9a.[2] The court stated that information is deemed "material" if there is "a substantial likelihood that a reasonable examiner would have considered the information important in deciding whether to allow the application to issue as a patent." *Id.* 10a. The court said that a declarant's past relationship with a patent applicant meets that materiality standard whenever: (1) the declarant's views on "the underlying issue" are material; and (2) the relationship to the applicant "was a significant one." *Id.* 13a-14a. The court determined that those standards had been met in this case. *Id.* 14a.[3] The appeals court's determination that the omissions were "highly" material, *id.* 14a and 18a, included no discussion of the declarations of Dr. Miller. Dr. Miller, whose lack of a relationship with Ferring has never been disputed, largely replicated the opinions contained in the disputed declarations.

The appeals court also determined that the applicant's omissions were made with an intent to deceive. *Id.* 18a-24a. While conceding the absence of any direct evidence of such intent, the court said that intent could be inferred, even at the

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[2] The appeals court stated that the district court's materiality and intent findings were subject to *de novo* review. *Id.* 10a.

[3] The court said that "the omitted affiliation with respect to Robinson in particular was highly material since Robinson had actually been employed by Ferring." *Id.* 25a.

summary judgment stage, when the omitted information is "highly material" and: (1) the applicant knew of the information; (2) the applicant knew "or should have known" of its materiality; and (3) the applicant has not provided "any credible explanation for the withholding." *Id.* 19a. The court said that all those conditions had been met. *Id.*

The appeals court expressed no opinion regarding whether the PTO's decision would have been affected if Dr. Vilhardt had disclosed the three declarants' past relationships with Ferring, stating: "While we will never know how the examiners may have weighed the declarations differently, it seems clear to us that this stellar showing of support would have, at the very least, been tarnished." *Id.* 26a. Finally, the appeals court held that the district court's "ultimate finding of inequitable conduct" was not an abuse of discretion. *Id.*[4]

Judge Newman dissented. *Id.* 28a-49a. Disagreeing with both the materiality and intent findings of the majority, Judge Newman charged that the majority had "replac[ed] the need for evidence with a 'should have known' standard of materiality, from which deceptive intent is inferred, even in the total absence of evidence." *Id.* 32a. She noted, "There is no evidence, or even an allegation, that any of these scientists [*i.e.*, Drs. Czernichow, Robinson and Barth] had anything to gain or lose as a result of issuance of the [Ferring] patent." *Id.* 35a.

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[4] The appeals court did not address the district court's alternative holding that Barr did not infringe the Ferring patent.

REASONS FOR GRANTING THE PETITION

This case raises patent law issues of exceptional importance. While allegations of inequitable conduct are easily made, any such ruling overturns the PTO's decision to allow a patent and has enormous practical and financial consequences for the parties involved.[5] WLF agrees with Petitioners that review is warranted on both of the questions presented; we write separately to focus particular attention on the need for this Court to address the types of "material" omissions that warrant judicial refusal to enforce an otherwise valid patent.

Review is warranted because the Federal Circuit has departed so fundamentally from this Court's rationale for creating an "inequitable conduct" defense to a patent infringement claim. As the Court explained more than 60 years ago, "[t]he guiding doctrine" in patent cases in which inequitable conduct is alleged "is the equitable maxim that 'he who comes into equity must come with clean hands.'" *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806, 814 (1945). The "unclean hands" doctrine "closes the doors of a court of equity to one tainted with inequitableness or bad faith relative to the matter in which he seeks relief." *Id.* An important limitation on application of the unclean hands doctrine is that it has never been applied to a plaintiff based simply on the fact that the plaintiff has engaged in misconduct; rather, the doctrine is strictly limited to situations in which some unconscionable act

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[5] One non-obvious consequence is potentially ruinous litigation: patent holders whose patents are overturned based on findings of inequitable conduct routinely are hit with numerous antitrust class actions alleging that they drove up prices by improperly restraining competition.

committed by the plaintiff has *immediate and necessary* relation to the equity he seeks.

One searches the Federal Circuit's "inequitable conduct" decisions in vain for any indication that that court is basing its decisions on anything remotely resembling the "unclean hands" approach mandated by *Precision Instrument.* Instead, the Federal Circuit has developed an elaborate set of rules for determining when omitted information should be deemed material and when the patentee should be deemed to have acted with the requisite intent. All too frequently, the result of those rules has been travesties such as the decision at issue here: a patent is struck down based on alleged "inequitable conduct" despite *the absence of even an allegation* that any of the information submitted in support of the patent was false or misleading. By interpreting materiality so broadly, the Federal Circuit in essence is attempting to write the rules of evidence for the PTO; such rules have little relationship to the "unclean hands" doctrine and – because they are being written after the fact – have thrown into doubt the validity of numerous existing patents. Review is warranted to resolve the sharp conflict between this Court's understanding of "inequitable conduct" and the Federal Circuit's recent "inequitable conduct" decisions.

Review is also warranted because of the tremendous uncertainty among patent holders being created by the Federal Circuit's inequitable conduct decisions. At the same time that the Federal Circuit is inexorably expanding the definition of a "material" omission, it has declined to provide precise guidelines regarding what evidence must be submitted to the PTO and has made absolutely clear that it does not deem itself bound by any evidentiary rules established by the PTO. The result is that applicants must guess regarding what evidence must be submitted, with the potential penalty for a wrong

guess being the invalidation of an otherwise valid patent. Moreover, given the Federal Circuit's demonstrated willingness to apply its broadened standards to patents issued 15 or more years ago, an applicant's guessing game entails determining not only what the Federal Circuit might deem "material" today but also what it might deem "material" 15 years from now. Review is warranted to permit this Court to establish a readily comprehensible inequitable conduct standard on which applicants can rely.

Finally, there is no merit to Barr's contention that Petitioners have in some manner waived their right to challenge the Federal Circuit's materiality and intent standards. Throughout these proceedings, Petitioners have contested allegations that information omitted from the Ferring Patent application was material and that those alleged omissions were undertaken with an intent to deceive the PTO. By raising those issues below, Petitioners have preserved the right to raise them again in this Court – and to introduce any and all arguments relevant to those issues, including arguments that the Federal Circuit's broad definitions of materiality and intent are inconsistent with this Court's approach to "inequitable conduct" cases.

I. REVIEW IS WARRANTED BECAUSE THE DECISION BELOW CONFLICTS WITH THIS COURT'S UNDERSTANDING OF WHAT CONSTITUTES "INEQUITABLE CONDUCT"

It has now been more than 60 years since the Court last addressed the circumstances under which an otherwise-valid patent should be held unenforceable based on the applicant's inequitable conduct before the Patent Office. That case, *Precision Instrument,* held a patent unenforceable based on findings that: (1) Automotive, the applicant, learned that a

competing applicant had committed perjury during interference proceedings; (2) Automotive used that information to blackmail the competing applicant into assigning his patent rights to Automotive and agreeing never to contest the resulting patent; (3) Automotive never revealed the patent's fraudulent ancestry to the Patent Office; and (4) the result of its actions was that Automotive was issued a patent with claims broader than those to which Automotive was actually entitled. *Precision Instrument*, 324 U.S. at 818-19. The Court held that those facts "all add up to the inescapable conclusion that Automotive has not displayed that standard of conduct requisite to the maintenance of this suit in equity," and it applied the "unclean hands" doctrine to deny enforcement of any part of the patent. *Id.* at 819.

As Petitioners note, in the ensuing decades the federal appeals courts struggled to determine just how close the relationship between omitted information and issues raised in PTO proceedings must be[6] before the omission can be deemed sufficiently material to warrant application of the "unclean hands" doctrine. Pet. 17-18. The appeals courts developed at least three conflicting standards of materiality. *Id.* But following creation of the Federal Circuit, that court chose to adopt none of the three competing definitions of materiality and instead adopted its own, broader definition: information is deemed material where there is "a substantial likelihood" that a reasonable examiner would consider it "important" in deciding to allow the application to issue as a patent. *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1362 (Fed. Cir. 1984). In ensuing years, the Federal Circuit has repeatedly expanded its definition of the

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[6] Or between an affirmative misrepresentation and issued raised in PTO proceedings.

information a reasonable examiner would consider important, so that now, as illustrated by the decision below, virtually *any* information that bears on the credibility of any evidence submitted to the PTO on a contested issue is deemed material.

That standard of materiality bears little resemblance to "unclean hands" doctrine and conflicts sharply with this Court's understanding of what constitutes "inequitable conduct." In particular, the Federal Circuit's materiality standard fails to heed this Court's admonition regarding strict limits on application of "unclean hands" doctrine:

> But courts of equity do not make the quality of suitors the test. They apply the maxim requiring clean hands only where some *unconscionable* act of one coming for relief has *immediate and necessary relation* to the equity that he seeks in respect of the matter in litigation.

Keystone Driller Co. v. General Excavator Co., 290 U.S. 240, 245 (1933) (emphasis added).

In *Keystone Driller*, the Court applied "unclean hands" doctrine to dismiss a patent infringement action, where the evidence showed that: (1) an individual may have engaged in prior use of the claimed invention (a circumstance which, if true, would have invalidated a patent); (2) following issuance of the patent, the patentee paid the individual not to disclose his prior use and to sign an affidavit stating that his use of the device was merely an abandoned experiment; and (3) the individual failed to disclose these arrangements in his subsequent deposition. *Id.* at 243. But in other cases, the court has declined to apply "unclean hands" doctrine where the plaintiffs' misconduct did not have a sufficiently "immediate and necessary relation" to the equitable relief sought, to warrant non-enforcement of the patent. *See, e.g., Corona*

Cord Tire Co. v. Donovan Chemical Corp., 276 U.S. 358, 373-74 (1928) (applicant's submission of false affidavits to Patent Office did not warrant non-enforcement of patent, because the falsehoods were not crucial to issuance of the patent).

In more recent times, the Court upheld the NLRB's decision not to apply the "unclean hands" doctrine to bar reinstatement of a fired employee, despite the employee's perjured testimony regarding the reason he was late for work. *Air Freight System, Inc. v. NLRB*, 510 U.S. 317 (1993). The NLRB had reasoned that the perjury was not sufficiently material to the issue of reinstatement, because (the NLRB determined) the employee had actually been fired in retaliation for union activity, not (as the company alleged) because of his tardiness. *Id.* at 321. Similarly, the Fourth Circuit declined to apply the "unclean hands" doctrine to bar an award of equitable relief to a foreign government accused of persecuting a political opponent, where there was no "close nexus between a party's unethical conduct and the transactions on which that party seeks relief." *Republic of Rwanda v. Uwimana*, 274 F.3d 806, 810 (4th Cir. 2001) (citing *Keystone Driller*).

The Federal Circuit's determination in this case – that virtually any evidence that bears on credibility of material evidence should itself be deemed material for purposes of adjudicating "inequitable conduct" claims – cannot be squared with *Precision Instrument* and *Keystone Driller*. Such credibility evidence can rarely, if ever, be deemed to bear an "immediate and necessary relation" (*Keystone Driller*, 290 U.S. at 245) to whether the Ferring Patent should have been issued. Even if the Federal Circuit were correct that a reasonable examiner would have thought it "important" that Drs. Czernichow, Robinson, and Barth had prior professional relationships with Ferring, such evidence is sufficiently

tangential to the accuracy of their declarations that it cannot meet *Keystone Driller*'s "immediate and necessary relation" test. That is particularly true where, as here, there is no evidence in the record seriously calling into question the accuracy of their declarations.[7]

The declarants' prior professional relationships with Ferring is rendered all the more tangential when one considers that their testimony was cumulative. Dr. Miller provided declarations stating that neither the Zaoral Patent nor the Vavra reference, nor the two of them in tandem, suggested oral administration of DDAVP for gastrointestinal absorption. Dr. Miller's lack of a prior relationship with Ferring has never been questioned. Because his testimony covered the same ground covered by the Czernichow, Robinson, and Barth declarations, there is little reason to suppose that an examiner would have reached a different patenting decision even if he or she had totally discounted the other three declarations for bias. Indeed, the PTO explicitly excludes, from its own definition of "material" information, any information that is "cumulative to information already of record or being made of record in the application." 37 C.F.R. § 1.56(b), Pet. App. 96a.

The appeals court nonetheless made clear that it considers a declarant's past relationship with a patent applicant

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[7] That assessment does not change simply because an examiner in 1986 recommended to Dr. Vilhardt that he obtain "non-inventor" statements (a recommendation not repeated when Dr. Vilhardt collected his second round of declarations four years later). Dr. Vilhardt literally complied with that request: none of the declarants other than Dr. Vilhardt was an inventor of the claimed invention. Moreover, the prior relationships that Drs. Czernichow, Robinson, and Barth had with Ferring made them far less interested witnesses than if, for example, they were being paid for their testimony or if they stood to profit from the patenting or marketing of the claimed invention.

to be "material" *whenever* the declarant's views are material to a contested issue in the application process and the relationship is a "significant" one. Pet. App. 13a-14a. Indeed, the appeals court for some unspecified reason determined that the past relationships in this case (particularly Dr. Robinson's) were "highly material," *id.* 18a and 25a, a determination that caused the appeals court to apply a relaxed standard for finding "intent" to deceive. The court made clear that this expansive definition of "material" applies to any evidence of past relationships between a declarant and a patent applicant, regardless of whether the declarant's statements are cumulative. Review is warranted to resolve the conflict between that Federal Circuit standard and this Court's admonition that the "unclean hands" doctrine only applies when *Keystone Driller*'s "immediate and necessary relation" test is met.

II. REVIEW IS WARRANTED BECAUSE OF THE TREMENDOUS UNCERTAINTY BEING CREATED BY THE FEDERAL CIRCUIT'S INEQUITABLE CONDUCT DECISIONS

As Petitioners have well documented, the Federal Circuit's expansion of the inequitable conduct doctrine far beyond its unclean hands origins has led to inclusion of inequitable conduct defenses in virtually all patent infringement actions. Pet. 12-13. The Federal Circuit itself has described the proliferation of such claims as "an absolute plague" on the patent system. *Burlington Industries, Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988). The Federal Circuit attempted to address that problem a number of years ago by tightening somewhat the standards for establishing that a patent applicant intended to deceive the PTO. *See Kingsdown Medical Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 876-77 (Fed. Cir. 1988) (*en banc*). But

Kingsdown did not address the Federal Circuit's overly broad materiality standard, and in the intervening years, the circuit's definitions of materiality and intent have only grown more encompassing. As Judge Newman argued in dissent, the majority:

> [N]ot only ignore[s] *Kingsdown* and restore[s] a casually subjective standard, they also impose a positive inference of wrongdoing, replacing the need for evidence with a "should have known" standard of materiality, from which deceptive intent is inferred, even in the total absence of evidence. Thus the panel majority infers material misrepresentation, infers malevolent intent, presumes inequitable conduct, and wipes out a valuable property right, all on summary judgment, on the theory that the inventor "should have known" that something might be deemed material.

Pet. App. 32a.

It is difficult to overestimate the chilling effect that such decisions have on the research and development activities that the patent system is intended to foster. If the business community loses faith in the willingness of courts to uphold patents, they are unlikely to be willing to continue to invest the hundreds of millions of dollars typically required to bring a new drug through research and testing and eventually to obtain marketing approval. Indeed, the costs and uncertainties associated with application of the inequitable conduct doctrine led the National Research Council of the National Academies of Science and Engineering in 2004 to recommend "the elimination of the inequitable conduct doctrine or changes in its implementation." National Research Council, *A Patent System for the 21st Century* (2004) at 123, http://www.nap.

edu/html/patentsystem/0309089107.pdf. Review is warranted to prevent the Federal Circuit's inequitable conduct standards from further eroding confidence in our patent system.

The practical problems created for patent applicants by the decision below are readily apparent. Because the Federal Circuit has made plain that it does not feel bound by the PTO's own evidentiary rules in determining what evidence is "material" for inequitable conduct purposes, patent applicants cannot seek guidance from the PTO's rules – which, since at least 1992, have defined materiality considerably more narrowly than does the Federal Circuit. *See* 37 C.F.R. § 1.56, Pet. App. 95a-97a. The decision below puts applicants on notice that *any* evidence relevant to credibility might later be deemed material for purposes of evaluating inequitable conduct claims, because all such evidence might be deemed likely to "interest" a reasonable examiner. For example, since Rule 609 of the Federal Rules of Evidence states that evidence of a criminal conviction is always admissible to impeach witness credibility, applicants may be faulted in future Federal Circuit inequitable conduct decisions for having failed to disclose every criminal conviction of every individual whose declaration is submitted to the PTO. Similarly, despite Fed.R.Civ.P. 26(b)(4), applicants might be faulted for failing to disclose the opinions of non-testifying experts.

While the court below stated that applicants must disclose every "significant" relationship between a declarant and an applicant, it provided little or no guidance regarding what is meant by "significant." Is a friendship between the declarant and the inventor sufficient? What if the declarant and the inventor once worked for the same company, but not the company to whom the patent application has been assigned? What if the inventor in the past signed a declaration that assisted the declarant in obtaining a separate patent of her

own? One might ordinarily think the answer to those questions is "no"; but in light of the decision below – in which a patent was invalidated on the basis of nondisclosure of past relationships under which the declarants had nothing to gain by issuance of the patent – applicants are left with a tremendous amount of uncertainty. In areas of this type, a bright-line rule of some sort – regardless of the form that rule finally takes – is superior to the confusion sown by the current, ill-defined rule. Review is warranted to permit the Court to develop a bright-line rule that will provide clearer guidance to patent applicants.

WLF is not suggesting that applicants need to be provided greater leeway to hide damaging evidence from patent examiners. Indeed, if the PTO determines that it would like applicants to disclose the types of relationships that existed between the declarants and Ferring in this case, WLF would have no objection to the PTO's adoption of an evidentiary rule to that effect. What WLF finds objectionable is the Federal Circuit arrogating to itself the power to write after-the-fact evidentiary rules for the PTO. Review is warranted to permit this Court to determine whether such after-the-fact draftsmanship has a proper place in "unclean hands" and inequitable conduct doctrine.

III. PETITIONERS HAVE NOT WAIVED THEIR RIGHT TO CHALLENGE THE FEDERAL CIRCUIT'S MATERIALITY AND INTENT STANDARDS

In its brief in opposition to the petition, Barr argued that Petitioners have waived their right to challenge the federal circuit's materiality and intent standards. Opp. Br. 13-16. That argument is without merit.

Throughout these proceedings, Petitioners have contested allegations that information omitted from the Ferring Patent application was material and that those alleged omissions were undertaken with an intent to deceive the PTO. By contesting those issues below, Petitioners have preserved the right to contest them again in this Court – and to introduce any and all arguments relevant to those issues, including arguments that the Federal Circuit's broad definitions of materiality and intent are inconsistent with this Court's approach to "inequitable conduct" cases. As the Court has repeatedly explained:

> Our traditional rule is that "once a federal claim is properly presented, a party can make any argument in support of that claim; parties are not limited to the precise arguments they made below."

Lebron v. National Railroad Passenger Corp., 513 U.S. 374, 379 (1995) (quoting *Yee v. City of Escondido*, 503 U.S. 519, 534 (1992)). *See also Harris Trust and Savings Bank v. Salomon Smith Barney Inc.*, 530 U.S. 238, 245 n.2 (2000).

A holding that Petitioners have waived materiality and intent arguments would be particularly inappropriate, because the panel below was, by and large, applying existing Federal Circuit law to the facts of this case and thus lacked authority – assuming it was so inclined – to overturn that existing law. Accordingly, it would serve no purpose to require those in Petitioners position – under threat of waiver – to raise below a challenge to existing Federal Circuit materiality and intent standards when that challenge would inevitably have been denied. It is sufficient that Petitioners throughout this litigation have contested claims that they failed to present material evidence to the examiners and that they did so with an intent to deceive.

Nor is there any merit to Barr's suggestion that the issues raised by Petitioners should be permitted to continue to percolate in the federal appeals courts before they are considered by this Court. Under existing law, the only appeals court that will ever hear patent law issues of this sort is the Federal Circuit. That court has repeatedly rebuffed efforts to scale back on its inequitable conduct case law to eliminate the "plague" of inequitable conduct claims. Delay will not make the issues raised by Petitioners any more suitable for review than they are today. This case provides a particularly suitable vehicle for addressing those issues: because the case comes to the Court on a grant of summary judgment, there are no disputed issues of fact. Rather, the evidence submitted by Petitioners is accepted as true, and all reasonable inferences are to be drawn in their favor. *See, e.g., Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986).

CONCLUSION

The Washington Legal Foundation respectfully requests that the Court grant the petition for a writ of certiorari.

Respectfully submitted,

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